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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

KERR, KATHLEEN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

15

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,350

Applicant(s)

SVENDSEN ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/032,315.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a Final rejection (Paper No. 9, mailed on January 24, 2003), Applicants filed an after-final amendment received on July 16, 2003 (Paper No. 13). Said after-final amendment has been entered; said amendment cancelled Claims 32-63 and added new Claims 64-95. Thus, Claims 64-95 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for U.S. non-Provisional Application Nos. 09/036,260 (USPN 6,184,015) filed on September 15, 1999 and 09/032,315 (USPN 5,985,818) filed on February 27, 1998 as well as the foreign application 0222/97 filed in Denmark on February 28, 1997 as requested in the declaration.

Terminal Disclaimer

3. The terminal disclaimer filed on July 16, 2003 (Paper No. 14) disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of USPN 5,985,818 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Withdrawn - Objections to the Specification

4. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicants' amendment.

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5. Previous objection to the Title for not completely describing the claimed subject matter is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Objections

6. Previous objection to Claims 32-63 for the improper Markush grouping is withdrawn by virtue of Applicants' cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

7. Previous rejection of Claims 32-63 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' cancellation of said claims.

Withdrawn - Double Patenting

8. Previous rejection of Claims 15-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, respectively, of U.S. Patent No. 5,985,818 in view of Yaver *et al.* (USPN 6,008,029) is withdrawn by virtue of Applicants' terminal disclaimer filed as noted above.

NEW REJECTIONS

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 64-95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. In Claim 64, the combination of semicolons and commas in the punctuation in the Markush group renders the claim unclear. Are all the members of the Markush group equal in importance? Clearly D106A and D106F cannot be mutated in the same variant. The Examiner suggests commas to separate all the members of the Markush group with a semicolon at the end, before the “wherein” phrase.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 64-95 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to variants of a particular laccase having mutations in particular positions relative to SEQ ID NO:10. These mutations cause altered activities. However, the claimed enzymes have no definite structure as claimed. Particular, the “variant” claimed could have *any number of mutations* relative to SEQ ID NO:10 so long as the particular mutations noted are also encompassed by the enzyme.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject

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matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification fully describes a subgenus of the claimed genus. This subgenus contains SEQ ID NO:10 mutated *only* at the positions noted in Claim 64. This subgenus does not contain all possible laccase sequences having any sequences as long as they have the residues noted in Claim 64 as correlated to SEQ ID NO:10. The specification does not describe the common characteristics of the claimed molecules in definite structural and functional terms. In other words, one of skill in the art would be unable to construct a laccase using SEQ ID NO:10 as a basis without knowing which residues were important to the laccase activity and which were not. While one might be enabled to perform such random mutations of a protein, the genus of mutants with laccase activity has not been structurally described. Thus, one of skill in the art would be unable to predict the structures of the claimed genus of molecules.

The Examiner notes that this rejection has previously been set forth against pending claims and withdrawn when Applicants added the phrase “wherein the laccase has an amino acid sequence of SEQ ID NO:10”. The Examiner mistakenly interpreted this phrase as limiting the

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claimed **variant**; this mistaken interpretation lead to the withdrawal of the rejection previously. However, the claim language only limits the base structure onto which an unlimited number of mutations can be performed; this interpretation warrants the instant written description rejection. This is clearly the intended interpretation since Applicants state “since the transition word ‘comprising’ is used, the claimed variants may have one or more additional mutations that are not recited in the claims” (see Paper No. 13 filed July 16, 2003, Remarks, page 7).

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 64 and 68 are rejected under 35 U.S.C. § 102(b) as being anticipated by Germann *et al.* (see PTO-892 with Paper No. 7). The instant claims are drawn to a variant of SEQ ID NO:10 having an A108V mutation and any number of other mutations.

Germann *et al.* teach the amino acid sequence of laccase from *Neurospora crassa*. Said sequence, when aligned to SEQ ID NO:10 (see previously attached alignment), has the A108V mutation. Thus, the N. crassa sequence can be considered a mutant of SEQ ID NO:10 with numerous mutations, particularly the claimed mutation - A108V.

Summary of Pending Issues

12. The following is a summary of the issues pending in the instant application:
- a) Claims 64-95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
 - b) Claims 64-95 are rejected under 35 U.S.C. § 112, first paragraph, written description.
 - c) Claims 64 and 68 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Germann et al.* (see PTO-892 with Paper No. 7).

Allowable Subject Matter

13. The Examiner notes that clear claims, amended as suggested previously, would be allowable when drawn to variants having the exact sequence of SEQ ID NO:10 with only particular mutations noted. Language has been previously recommended to Applicants in previous Office actions; Applicants have repeatedly chosen to not adopt said language.

Conclusion

14. Claims 64-95 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL** based on the reiteration of the written description rejection, previously set forth but also previously withdrawn. Since it has been newly set forth herein due to a new interpretation of claim language previously set forth (in essence) by Applicants, the instant Office action is hereby non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

August 21, 2003

